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10/584,982	04/02/2007	Robin Kurfurst	15675P620	2408

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
11/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,982	KURFURST ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/14/09 & 4/22/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38,42-57 and 60-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38, 42-57, and 60-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Election filed September 14, 2009 and Applicant's Amendment and Remarks filed April 22, 2009.

Claims 38, 42-57, and 60-66 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election with traverse of an active agent that inhibits the activity of tyrosinase in the reply filed on September 14, 2009 is acknowledged. The traversal is on the ground(s) that the subject matter in claim 65 does not lack unity of invention because Applicants estimate that the use in a method for depigmenting or bleaching human skin, body hair and/or hair of a head of a subject to lighten a color for purely cosmetic purposes, comprising topical application to the skin, the body hair and/or the hair of the head of said subject of a cosmetic composition comprising at least one oligonucleotide having between 7 and 25 nucleotides, capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1 (PKC beta-1) wherein the composition further comprises at least one additional active agent that is a depigmenting substance constitutes a new and inventive technical feature which is common to all methods claimed in claim 65. In this regard, Applicants argue that claim 65 does not lack unity of invention.

Applicant's traversal has been fully considered by the Examiner. However, it should be noted that after careful reconsideration of the claims, the Examiner has decided to withdraw the Restriction Requirement mailed July 14, 2009. The Examiner has decided to withdraw the Restriction Requirement because the instant application is actually a 371 application and the Restriction Requirement mailed July 14, 2009 should not have been a restriction under 35 U.S.C. 121, but should have been a lack of unity according to PCT Rule 13.1 and 13.2. Nevertheless, the Examiner is withdrawing the Restriction Requirement mailed July 14, 2009 and claim 65 will be examined on the merits. Therefore, Applicant's traversal filed September 14, 2009 is moot.

Accordingly, claims 38, 42-57, and 60-66 will be examined on the merits.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed November 26, 2008, claims 38 and 42-57 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/02069 A1 ('069) (submitted and made of record on Applicant's Information Disclosure Statement filed November 20, 2006) as evidenced by Lazou et al. (submitted and made of record in the Office Action filed February 5, 2008). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed November 26, 2008.

Response to Arguments

In response to this rejection, Applicants respectfully submit that not all of what is disclosed in Bennett (WO 95/02069) is prior art to the present patent application. Applicants contend that the present patent application claims priority to December 30, 2003. Bennett (WO 95/02069) derives priority from U.S. Patent Application Serial No. 08/199,779 filed on February 22, 1994, and the '779 application is itself a continuation-in-part (CIP) of U.S. Patent Application Serial No. 07/081,996, which was filed July 9, 1993. Applicants contend that it is well known that new subject matter may be added to a CIP application, and that such newly added subject matter is not entitled to the priority date. Accordingly, any new matter added to Bennett (WO 95/02069), which was not present in U.S. Patent Application Serial No. 07/081,996, should not be entitled to the July 9, 1993 priority date of the '996 patent application. Applicants therefore request that the Examiner either abstain from using the claims of Bennett (WO 95/02069) in the rejections, or else show with specificity where each of these claims has unambiguous support in the '996 patent application. Applicants also request that the Examiner rely upon U.S. Patent No. 5,703,054 instead of Bennett (WO 95/02069).

This response has been fully considered, but is not found persuasive by the Examiner. It should be noted that while WO 95/02069 derives priority from U.S. Patent Application Serial No. 08/199,779 filed on February 22, 1994, and the '779 application is itself a continuation-in-part (CIP) of U.S. Patent Application Serial No. 07/081,996, which was filed July 9, 1993, WO 95/02069 is the only reference present in the rejection

of record. In fact, this reference is disclosed in Applicant's Information Disclosure Statement filed November 20, 2006.

U.S. Patent Application Serial No. 08/199,779, U.S. Patent Application Serial No. 07/081,996, or U.S. Patent No. 5,703,054 are not, and have not been relied upon by the Examiner in the instant 103 rejection of record. WO 95/02069 is the only reference present in the rejection of record. Therefore, the Examiner has, and will continue to use the disclosures found in the WO patent to maintain the rejection(s) of record. In this regard, Applicants request that the Examiner rely upon U.S. Patent No. 5,703,054 instead of Bennett (WO 95/02069) is unfounded and is denied.

Applicants next argue that Bennett (WO 95/02069) as evidenced by Lazou does not disclose the limitations of Applicant's claims or render them obvious. Applicants contend that instead, Bennett discusses administration of oligonucleotides for the treatment and diagnosis of disease, where such treatment and diagnosis of disease is not application of a cosmetic composition for depigmenting or bleaching human skin, body hair and/or hair of a head of a subject to lighten a color for purely cosmetic purposes, as recited in Applicant's claims.

This argument has been fully considered by the Examiner, but is not found persuasive. While it is acknowledged that WO 95/02069 (Bennett) discusses administration of oligonucleotides for the treatment and diagnosis of disease (see Abstract), WO 95/02069 also discusses and claims administration of PKC beta-1 oligonucleotides for treating a condition associated with expression of PKC (see claims

70, 85, and 89, for example). As noted by Park et al. (Journal of Biological Chemistry, 1993 Vol. 268:16:11742-11749, submitted and made of record on Applicant's Information Disclosure Statement filed November 20, 2006), at the time of invention, it was known that PKC-β is associated with pigmentation. For example, Park et al. teach that PKC-β mRNA is detected in pigmented human cells, but not in a nonpigmented subclonal cell line (see Abstract). Park et al. also disclose:

> "Black donor cultures expressed far more PKC-β than did the more lightly pigmented white donor cultures". See page 11748, first column, first few lines.

Therefore, given the teachings of WO 95/02069, combined with what was known in the art at the time of filing, one of ordinary skill in the art would associate depigmenting with a condition associated with expression of PKC.

Applicants next argue that WO 95/02069 (Bennett) do not disclose topical application to the skin, the body hair and or the hair of the head a composition comprising at least one oligonucleotide capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1).

This argument has been fully considered, but is not found persuasive because contrary to Applicant's arguments, WO 95/02069 indeed discloses topical application to the skin, the body hair and or the hair of the head a composition comprising at least one oligonucleotide capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1). For example, see claims 70-72, 76, 86, and 89, which disclose a method of treating psoriasis or skin cancer comprising

administering a composition comprising at least one oligonucleotide capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1).

Applicants next argue that it is clear from WO 95/02069 (Bennett) that PKC represents a complex family of isozymes and that particular PKC associated conditions are actually associated to one or more specific isozymes. Therefore, Applicants contend that is clear from WO 95/02069 (Bennett) that an effective treatment will not be obtained using antisense oligonucleotides specifically hybridizable with any PKC isozyme, but only using antisense oligonucleotides specifically hybridizable with the adequate PKC isozyme.

This argument has been fully considered, but is not found persuasive because WO 95/02069 clearly and explicitly disclose a method of treating psoriasis or skin cancer comprising administering a composition comprising at least one oligonucleotide capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1). See claims 70-72, 76, 86, and 89, for example. Therefore, WO 95/02069 is explicit and clear that such methods are obtained using antisense oligonucleotides specifically hybridizable to PKC beta-1.

Applicants next argue that WO 95/02069 (Bennett) discusses using oligonucleotides to treat psoriasis and skin cancer, however Bennett does not disclose that psoriasis or skin cancer are associated with an increase in PKC beta-1 expression.

This argument has been fully considered by the Examiner, but is not found

persuasive because it appears that Applicants are arguing against limitations that are not recited in the instant claim(s). Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, Applicants arguments regarding an increase in PKC beta-1 expression appear to be misplaced since the claims do not recite or even require an increase in PKC beta-1 expression. Instead, the claims only require that an oligonucleotide capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1) is topically administered to a subject. As noted above, WO 95/02069 discloses this method step. Therefore, the claims are obvious over WO 95/02069.

Applicants next argue that Bennett (WO 95/02069) as evidenced by Lazou does not disclose topical application to the hyper-pigmented skin areas at least one oligonucleotide capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1), as recited in Applicant's claims.

This argument has been fully considered by the Examiner, but is not found persuasive because WO 95/02069 discusses and claims administration of PKC beta-1 oligonucleotides for treating a condition associated with expression of PKC (see claims 70, 85, and 89), wherein the condition is a hyperproliferative skin disorder. As noted by Park et al. (Journal of Biological Chemistry, 1993 Vol. 268:16:11742-11749, submitted and made of record on Applicant's Information Disclosure Statement filed November 20, 2006), PKC-β is associated with pigmentation. For example, Park et al. teach that PKC-

β mRNA is detected in pigmented human cells, but not in a nonpigmented subclonal cell line (see Abstract). Park et al. also disclose:

> "Black donor cultures expressed far more PKC-β than did the more lightly pigmented white donor cultures". See page 11748, first column, first few lines.

Therefore, given the teachings of WO 95/02069, combined with what was known in the art at the time of filing, one of ordinary skill in the art would associate hyper-depigmentation with a condition associated with expression of PKC.

Furthermore, the Examiner acknowledges that WO 95/02069 is largely silent as to whether or not their method of treating a condition associated with the expression of PKC specifically depigments or bleaches human skin. However, it is the Examiner's position that the topical administration to the skin of an oligonucleotide being specifically hybridizable with a PKC gene or PKC mRNA, including a PKC-beta 1 specific oligonucleotide, as disclosed by 'WO 95/02069, would inherently depigment or bleach human skin, as evidenced by Lazou et al. who teach that the topical administration of antisense oligonucleotides targeted to PKC-beta 1 lightens and whitens skin (see Abstract and Table 1). Therefore, absent evidence to the contrary, the topical administration to the skin of an oligonucleotide being specifically hybridizable with a PKC-beta 1 as disclosed by WO 95/02069 would inherently depigment or bleach human skin.

Even further, in the previous Office Action mailed November 26, 2008, the Examiner noted, because the methods recited in the prior art and Applicant's method for depigmenting or bleaching human skin recite the same method step, namely the topical

application to a subject a composition comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1, it is the Examiner's position that the methods steps recited in the prior art would inherently carry out the method step as claimed in Applicant's invention, as evidenced by Lazou et al., absent evidence to the contrary. That is, the method of topically administering an oligonucleotide specifically hybridizable with a PKC-beta 1 taught by WO 95/02069 would inherently depigment or bleach human skin as instantly claimed in Applicant's invention, absent evidence to the contrary. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986).

In providing evidence to the contrary, Applicants have provided only mere arguments that WO 95/02069 fails to disclose the claimed methods. Applicant is reminded that arguments of counsel alone cannot take the place of evidence in the record. See MPEP §2106. These arguments alone are not enough to satisfy factual evidence that is required.

In view of the foregoing, when all the evidence is considered, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness made of record. Thus, it is maintained that the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was filed.

Applicant's Amendment filed April 22, 2009 necessitated the new grounds of rejection presented below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 60-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/02069 A1 (submitted and made of record on Applicant's Information Disclosure Statement filed November 20, 2006) as evidenced by Park et al. (Journal of Biological Chemistry, 1993 Vol. 268:16:11742-11749, submitted and made of record on Applicant's Information Disclosure Statement filed November 20, 2006).

Claims 60-66 are drawn to a method of depigmenting or bleaching human skin, body hair and/or hair of a head of a subject to lighten a color for purely cosmetic purposes comprising topical application to the skin, the body hair and/or the hair of the head of said subject of a cosmetic composition comprising at least one oligonucleotide having between 7 and 25 nucleotides, capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1), wherein the topical

application comprises application of the composition to the hair of the head or the face; wherein the application of the composition comprises application of a makeup; wherein the composition comprises an SPF protective fluid; wherein the composition further comprises at least one additional active agent that is a depigmenting substance; wherein the active agent is selected from substances that inhibit the activity of tyrosinase; and wherein the topical application to the skin, the body hair and/or the hair of the head does not comprise skin having psoriasis or skin cancer.

Determining the scope and contents of the prior art

WO 95/02069 clearly and explicitly teach a method of treating psoriasis or skin cancer comprising administering a composition comprising at least one oligonucleotide capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1). See claims 70-72, 76, 86, and 89, for example. WO 95/02069 also discusses and claims administration of PKC beta-1 oligonucleotides for treating a condition associated with expression of PKC (see claims 70, 85, and 89).

Ascertaining the differences between the prior art and the claims at issue

WO 95/02069 does not explicitly teach that the topical application comprises application to the face, application of a makeup, or application of an SPF protective fluid. However, Applicant is reminded that with the decision in KSR International v. Teleflex Inc. (82 USPQ2d 1385) it was established that, "Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art."

WO 95/02069 teaches that the oligonucleotides of their invention are administered topically. WO 95/02069 also explicitly teaches:

> "Topical administration may include ointments, lotions, creams, gels, drops, suppositories, sprays, liquids and powders. Conventional pharmaceutical carriers, aqueous, powder or oily bases, thickeners and the like may be necessary or desirable. Coated condoms or gloves may also be useful"

Therefore, using general knowledge, one of ordinary skill in the art would understand that makeup and SPF protective fluid are encompassed in the disclosure of ointments, lotions, creams, etc. as taught in WO 95/02069.

WO 95/02069 also does not explicitly teach administering an active agent selected from substances that inhibit the activity of tyrosinase. However, Park et al. teach that inhibition of PKC-β inhibits tyrosinase activity. Therefore, oligonucleotides capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1) and other PKC-β inhibitors, such a cyclosporine A, which is associated with carnitin, disclosed by WO 95/02069 would be expected to inhibit tyrosinase activity, absent evidence to the contrary.

Resolving the level of ordinary skill in the pertinent art

The level of ordinary skill in the pertinent art is considered to be high, being a graduate student or post-doctoral fellow in a biological science.

Considering objective evidence present in the application indicating obviousness or nonobviousness

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made to devise a method of depigmenting or bleaching human skin, body hair and/or hair of a head of a subject to lighten a color for purely cosmetic

purposes comprising topical application to the skin, the body hair and/or the hair of the head of said subject of a cosmetic composition comprising at least one oligonucleotide having between 7 and 25 nucleotides, capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1) using the teachings of WO 95/02069. It would have been *prima facie* obvious to one of ordinary skill in the art to have the topical application comprises application to the face, application of a makeup, or application of an SPF protective fluid using the teachings of WO 95/02069 combined with general knowledge and understanding of one of ordinary skill in the art.

One of ordinary skill in the art would have been motivated to devise a method of depigmenting or bleaching human skin, body hair and/or hair of a head of a subject to lighten a color for purely cosmetic purposes comprising topical application to the skin, the body hair and/or the hair of the head of said subject of a cosmetic composition comprising at least one oligonucleotide having between 7 and 25 nucleotides, capable of specifically hybridising with genes or gene products coding for protein kinase C beta-1 (PKC beta-1) since WO 95/02069 taught that such a method could treating conditions associated with expression of PKC.

One of ordinary skill in the art would have had a reasonable expectation of success of devising a method of depigmenting or bleaching human skin, body hair and/or hair of a head of a subject to lighten a color for purely cosmetic purposes comprising topical application to the skin, the body hair and/or the hair of the head of said subject of a cosmetic composition comprising at least one oligonucleotide having between 7 and 25 nucleotides, capable of specifically hybridising with genes or gene

products coding for protein kinase C beta-1 (PKC beta-1) since, at the time of filing, the topical delivery of antisense oligonucleotides was routine and successful in the art.

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

November 15, 2009
/Terra Cotta Gibbs/

/Sean R McGarry/

Primary Examiner, Art Unit 1635